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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,506	11/20/2003	Brian Anthony Whittle	WHIT3001C2JDB	5627
23364	7590	08/17/2006	EXAMINER	
BACON & THOMAS, PLLC 625 SLATERS LANE FOURTH FLOOR ALEXANDRIA, VA 22314			TATE, CHRISTOPHER ROBIN	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/716,506

Applicant(s)

WHITTLE ET AL.

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/750,848.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1103</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' election without traverse of Group I, claims 1-16, in the reply filed on 26 June 2006 is acknowledged. In addition, Applicants' election of the herbal combination defined by claim 8(a) is also acknowledged. Please note, upon further review by the Examiner, the election of species requirement is hereby withdrawn at this time (however, an Election of Species requirement may be deemed necessary at some later point depending upon how the claims are drafted in response to this or subsequent Office action).

Claims 1-16 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for treating atopic eczema, non-atopic eczema and psoriasis comprising particular combinations of demonstrated herbals (such as the various particular combinations recited in instant claim 8), does not reasonably provide enablement for a composition having such a therapeutic effect comprising any and all combinations of herbals from among those instantly recited, or for treating any and all undefined atopic disease with even the instantly demonstrated particular herbal combination. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants have reasonably demonstrated that particular combinations of the recited herbals are useful for treating atopic eczema, non-atopic eczema and psoriasis. However, the claims encompass the use of any and all of the vast number of herbal permutations defined by the claims (see, e.g., the plethora of potential herbal combinations encompassed by instant claim 1) for such treatment, as well as for treating any and all undefined atopic diseases with such combinations, which is clearly beyond the scope of the instantly demonstrated invention.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to prepare and utilize an herbal composition having the instantly claimed functional effect(s) other than the particular demonstrated herbal combinations (such as recited in claim 8) for treating atopic eczema, non-atopic eczema and psoriasis (but not for treating any and all undefined atopic diseases).

To overcome the above rejection and to hasten prosecution (as well as to obviate a potential Election of Species requirement in a future Office action), it is strongly suggested that the limitations of claim 8 be appropriately incorporated into claim 1 and that the preamble phrase "atopic disease" be amended to recite --atopic eczema--.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,676,975. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to herbal compositions for treating eczema and psoriasis comprising the same herbal ingredients therein. Further, please note that the instant claims encompass and/or are encompassed by claims 1-7 of US '975.

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,399,112. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to herbal compositions for treating eczema and psoriasis comprising the same herbal ingredients therein. Further, please note that the instant claims encompass and/or are encompassed by claims 1-11 of US '112.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 10-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Castleman (The Healing Herbs, 1991).

A composition - including a pharmaceutical composition- comprising one or more herbal extracts/decoctions from among those recited is claimed.

Castleman teaches a therapeutic licorice extract - e.g., prepared as an orally-administered water decoction (which is the same or essentially the same preparatory method as that instantly disclosed), whereby licorice is the only herbal therein (see, e.g., page 239 -third paragraph under the heading *R_x for Licorice*). The water reads upon a pharmaceutically acceptable carrier/diluent. Please note that the instantly claimed R_f values would be inherent to such a licorice water extract decoction if the licorice water extract decoction were freeze-dried and subjected to chromatography parameters - as instantly claimed. Further, the reference licorice water decoction would inherently be in an amount effective to provide the instantly claimed functional effects (such as recited in instant claim 12).

Therefore, the reference is deemed to anticipate the instant claims above.

With respect to the above USC 102 rejection, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed (e.g., to treat eczema or psoriasis), however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting - see, e.g., MPEP 2112. (Applicants should be aware that the same type of USC 102 rejection as discussed above could have been made over numerous other singular subset herbal extracts/decoctions from among those instantly claimed).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheehan et al. (Lancet, 1992) and Whittle (GB 2,254,783).

Sheehan et al. beneficially teach a Chinese herbal composition for treating atopic dermatitis comprising a standardized formulation containing a combination of the herbal extracts/decoctions recited in instant claim 1, as active ingredients therein. Sheehan et al. disclose that some of the herbals act as anti-inflammatory agents, some as anti-microbial agents, some as sedative agents, and at least one as an immunosuppressive agent (see entire document including page 14, under the heading *Treatment*, and the paragraph bridging the two columns on page 16). Sheehan et al. do not expressly teach using subsets/subcombinations of such herbal extracts/decoctions.

Whittle beneficially teaches herbal compositions for treating skin dermatological disorders such as eczema and psoriasis comprising various combinations of herbal extracts/decoctions which contain one or more of the instantly claimed herbal extracts/decoctions - as active ingredients therein, including a combination of *Paeonia rubra*, *Rehmannia glutinosa* and *Glycyrrhiza uralensis* (along with one additional herbal - i.e., *Ledebouriella sesloides*) - see, e.g., Example 3. Whittle also beneficially teaches that although Chinese medicine teaches that substantially all of the herbs within an herbal combination are necessary for activity, anti-eczema activity may reside in a restricted (limited) number of herbs (based upon their individual activity) within such combination - thus, unnecessary herbal material can be omitted therefrom. Whittle further discloses the activity provided by individual herbal ingredients - including the activities provided by various individual herbals from among those instantly claimed (see entire document including Abstract; page 2, line 26 - page 3, line 14; page 7, line 33 - page 8, line 10; Examples 1-11, and Table 1).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a pharmaceutical composition comprising one or more of the herbal ingredients disclosed by the cited references, as active ingredient(s) therein, for treating skin dermatitis (such as eczema or psoriasis) based upon the beneficial teachings provided therein with respect to the individual activities such herbals provide (as discussed by each of the cited references) and further based upon the beneficial provided by Whittle with respect to the use of restricted (limited) number of herbs (based upon their individual activity) within such combination. Please also note that the omission of an element and its function is obvious - e.g., if it is not desired and/or necessary (including, e.g., the omission of *Ledebouriella sesloides* from the herbal combination taught by Whittle in Example 3 therein). See, e.g., *Ex parte Wu*, 10 USPQ 2031, 1989 - MPEP 2144.04. The result-effective adjustment of particular conventional working conditions (e.g., using one or more particular combinations of herbal ingredients from among those instantly claimed, including one or more of the herbal extract/decoction ingredients beneficially taught by the cited references - based upon their well known individual activities against skin dermatitis disorders such as psoriasis and eczema, as disclosed therein) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher R. Tate
Primary Examiner
Art Unit 1655